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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,087	01/31/2002	Donna Mendrick	044921-5038-01	6811
9629	7590	12/14/2004		
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004				
EXAMINER LY, CHEYNE D				
ART UNIT		PAPER NUMBER		
1631				

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

10/060,087

Applicant(s)

MENDRICK ET AL.

Examiner

Cheyne D Ly

Art Unit

1631

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 November 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 60-74,88-92 and 94-110.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: See Continuation Sheet

Continuation of 2. NOTE: The introduction of "hepatotoxin" in claims 60 and 98 raises new issues that would require further consideration and/or search. It is noted that claim 108 previously recited "individual hepatotoxin model" which is different from the limitation of "the test agent is a hepatotoxin" or "hepatotoxin excipient." Therefore, the claim amendment has not been entered.

Continuation of 5. does NOT place the application in condition for allowance because:

Claims 88-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained with respect to claims 88-92, as recited in the previous office action mailed August 17, 2004.

#### RESPONSE TO ARGUMENT

Applicant's argument via claim amendments have been fully considered and found to be unpersuasive because of the non-entry of the claim amendments.

Claims 60-74, 88-92, and 94-110 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. NEW MATTER REJECTION.

This rejection is maintained with respect to claims 60-74, 88-92, and 94-110 as recited in the previous office action mailed August 17, 2004.

Specific to claim 60 or 88, Applicant's argument by pointed to support has been fully considered and found to be unpersuasive because the pointed disclosure provides written description basis support to a plurality of "cells" but not "a...cell" as recited by said claims.

Specific to claims 95-97, the limitations of "at least 10 genes", "at least 50 genes", and "at least 100 genes" of tables 3A-DD have not been found in the pointed to support. It is noted the pointed to support discloses "expression levels of about...from Tables 1-3" in page 16, [0070]. The tables recited in the instant claims are different from those disclosed in the specification. Further, the limitation of "at least" in the claims is different from "about" in the specification.

Claims 60-74 and 94-110 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory algorithm type subject matter.

This rejection is maintained with respect to claims 60-74 and 94-110, as recited in the previous office action mailed August 17, 2004.

#### RESPONSE TO ARGUMENTS

Applicant's argument via amendment has been fully considered and found to be unpersuasive due to the non-entry of the claim amendments as discussed above.


Claims 60-74, 88-92, 94, and 98-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friend et al. (US 6218122 B1) taken with Cunningham et al. (US 6372431 B1).

This rejection is maintained with respect to claims 60-74, 88-92, 94, and 98-110 as recited in the previous office action mailed August 17, 2004.

#### RESPONSE TO ARGUMENTS

Applicant's argument via the claim amendments of "hepatotoxin" have been fully considered and found to be unpersuasive because of the non-entry of said claim amendments as discussed above. Specific to the arguments for "distinctions between Friend et al. and Applicant's invention pointed out in the previous response", Applicant is directed the Examiner's response (pages 5-8) of the the Office Action, mailed August 17, 2004.

Continuation of 10. Other: Specific to reference number 51 of the IDS, filed October 18, 2002, a copy of the reference has not been received by the Office as discussed by Applicant. It is advised that Applicant resubmit said reference for consideration.



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DEC 11 2004